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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,202	12/01/2003	Richard M. Batch	61616	3293

24201 7590 12/01/2006

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
HOPKINS, CHRISTINE D	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,202	BATCH, RICHARD M.	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-17,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-17,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 May 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed September 6, 2006. Claims 1-6, 8-17 and 19-20 are now pending. The Examiner acknowledges amendments to claims 1-4, 8-15 and 19-20 as well as the cancellation of claims 7 and 18.

Claim Objections

2. Claim 11 is objected to because of the following informalities: at line 20 "analyze the compiled the parameter values" should apparently read --analyze the compiled parameter values--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 8-10, 12-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by McIlroy et al. (U.S. Patent No. 5,583,758). McIlroy et al. (hereinafter McIlroy) disclose a health care management system containing a database of diagnosis-based guidelines developed by medical professionals to be used in a clinical

decision process for a particular patient. Regarding claims 1, 3 and 9, McIlroy teaches a system for analyzing medical data from a plurality of patients having a memory **310** for storing the "medical treatment data," or guideline databases **330** (col. 4, lines 56-60). The medical treatment data is composed of treatments derived from previous regimens administered to patients (col. 5, lines 7-20) and an optimum treatment value associated with each parameter such as a particular drug administered for thrombophlebitis. In a particular instance, the program has recommended an IV course of heparin and coumadin, and a corresponding time to be administered (see Fig. 16). System **300** includes a processor that communicates with memory **310** and compiles the data collected which will be analyzed and subsequently implemented as a guideline to an administrator seeking a treatment plan based on the input of a patient's own parameters (col. 5, lines 21-31). The system will present a treatment option, or perhaps more than one, representing acceptable values for a selected treatment parameter based on questions answered in the guideline query to the administrator (col. 5, lines 32-51).

Regarding claims 2 and 8, a collection of the clinical data decisions is processed by system **300** and provides an aggregated set of statistics for all cases entered in the database (col. 7, lines 36-40). A distribution is established such that if the final treatment decision from the administrator falls outside of an already established guideline in the database, the system calls for a specialist review (col. 8, lines 33-43). Likewise, if the final treatment decision differs from the guideline treatment, the system **300** displays information regarding discrepancies found in the comparison of the two (col. 5, lines 61-65).

In view of claim 4, McIlroy teaches that the administrator may choose a treatment plan different from that recommended by the analysis generated by the processor after completion of a inputting a patient's data. Thus, the administrator's proposed treatment plan will be subjected to a course of review from other medical professionals and subsequently entered into the database if found reasonable (col. 13, lines 30-48 and col. 14, lines 8-12), thus continuously updating the guidelines based on new findings (col. 10, lines 13-16).

Regarding claim 5, the processor of system **330** is configured to generate a report of the comparison between the acceptable values for a treatment parameter and those which have already been compiled. For example, Fig. 24A displays a proposed treatment to a patient's input conditions (**4A**) based on a guideline recommended treatment which may be **4A**, **4B**, or **4C**.

Referring to claim 6, "the analysis," or treatment option, as taught by McIlroy, is generated in the form of a report on a screen as depicted in Fig. 16. Guideline treatments, which are selected, are highlighted on the screen (col. 12, lines 66-67 to col. 13, lines 1-7).

Regarding claim 10, the "medical treatment data" includes patient physiological data such as pain, redness and swelling in the case of thrombophlebitis (Fig. 18). The processor analyzes those parameters such as swelling, redness and pain against those already established in the database to arrive at an appropriate medical treatment guideline for one having particular symptoms associated with thrombophlebitis. The guideline generated and presented to the administrator provides "at least one optimum

value," such as the administration of coumadin no greater than 2 days after the administration of heparin through an IV course (Fig. 16).

Regarding claims 12, 14 and 20, McIlroy teaches the analysis of medical data from a plurality of patients via memory **310** used for storing the "medical treatment data," or guideline databases **330** (col. 4, lines 56-60). The medical treatment data is composed of treatments derived from previous regimens administered to patients (col. 5, lines 7-20) and an optimum treatment value associated with each parameter such as a particular drug administered for thrombophlebitis. In a particular instance, the program determines an IV course of heparin and coumadin, and a corresponding time to be administered by comparison with the pre-established guideline databases (see Fig. 16). System **300** includes a processor that communicates with memory **310** and compiles the data collected which will be analyzed and subsequently implemented as a guideline to an administrator seeking a treatment plan based on the input of a patient's own parameters (col. 5, lines 21-31). The system will present a treatment option, or perhaps more than one, representing acceptable values for a selected treatment parameter based on questions answered in the guideline query to the administrator (col. 5, lines 32-51).

Regarding claims 13 and 19, a collection of the clinical data decisions is analyzed by system **300** and provides an aggregated set of statistics for all cases entered in the database (col. 7, lines 36-40). A distribution is established such that if the final treatment decision from the administrator falls outside of an already established guideline in the database, the system calls for a specialist review (col. 8, lines 33-43).

Likewise, if the final treatment decision differs from the guideline treatment, the system **300** displays information regarding discrepancies found in the comparison of the two (col. 5, lines 61-65).

In view of claim 15, the administrator may choose a treatment plan different than that recommended by the analysis generated by the processor (hence, "adjusting" the acceptable values") after completion of a patient's input data. Thus, the administrator's proposed treatment plan will be subjected to a course of review from other medical professionals and subsequently entered into the database if found reasonable (col. 13, lines 30-48 and col. 14, lines 8-12), thus continuously updating the guidelines based on new findings (col. 10, lines 13-16).

Regarding claim 16, the processor of system **330** is configured to generate a report of the comparison between the acceptable values for a treatment parameter and those which have already been compiled. For example, Fig. 24A displays a proposed treatment to a patient's input conditions (**4A**) based on a guideline recommended treatment which may be **4A**, **4B**, or **4C**.

Referring to claim 17, "the analysis," or treatment option is generated in the form of a report on a screen as depicted in Fig. 16. Guideline treatments, which are selected, are highlighted on the screen (col. 12, lines 66-67 to col. 13, lines 1-7).

5. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Coutre (U.S. Patent No. 5,317,506). Coutre discloses an infusion management and pumping system whereby infusion prescriptions of patients are generated and monitored by a pharmacy management system. In accordance with claim 11, the system of Coutre includes many

infusion pumping systems (i.e. medication administration devices), one associated with a particular patient in the hospital (see col. 3, lines 67-68 and col. 4, lines 1-5); the infusion pumping system to include a database memory (col. 10, lines 15-16) that includes patient data information, and medication information such as allergies to prescribed drugs (col. 10, lines 25-39). With respect to the "central processor" recited in claim 11, the data received from the individual infusion systems of Coutre can be transferred to the pharmacy management system where it is stored in memory and can be processed further for analysis of medication usage (col. 14, lines 36-41). Furthermore, in reference to the "database" of claim 11, the database of Coutre is located in the pharmacy management system, and includes a drug database which will alert an administrator of incompatible drugs, thus representing "optimal values" for the operation of the medical administration device, or infusion pump in the instance of Coutre (col. 2, lines 16-19). Coutre also teaches an interface by which to transfer information to the "central processor", (i.e., hospital administration system or pharmacy management system) via a serial port and multiplexer or manual transfer (col. 14, lines 29-39). In addition, the "processor configured to compile the medical treatment data" of claim 11 is in accordance with that disclosed by Coutre. The stored infusion parameters can be selected by an administrator in the analysis, by considering a number of elements such as: total drug usage, total patient drug usage, drug concentration, etc. (col. 14, lines 37-47) selected from and run on the pharmacy management and hospital administration databases (elements 20-3 and 26-3 of Fig. 1, respectively).

Response to Arguments

6. Applicant's arguments filed September 6, 2006, with regard to claim objections have been fully considered and are persuasive in view of the cancellation. The objections of claims 7 and 8 has been withdrawn.

7. Applicant's arguments filed September 6, 2006, with respect to the rejection of claims 1-20 under 35 U.S.C. 102(b) citing Coutre ('506) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing McIlroy et al. McIlroy et al. disclose a processor configured to determine a treatment regimen composed of "acceptable values" for a particular patient according to pre-established guidelines stored in a database based on a comparison between a patient's input data and the data previously established in the guideline database.

8. Applicant's arguments filed September 6, 2006, with respect to the rejection of claim 11 under 35 U.S.C. 102(b) citing Coutre ('506) have been fully considered but are not persuasive. Applicant contends that Coutre fails to teach a processor configured to determine a medical treatment guideline in accordance with an analysis of the complied treatment values from data associated with medication delivered to patients. However, this argument is not persuasive. Coutre teaches that the pharmacy management system having a database of drugs prescribed to patients, also processes drug information for a particular patient such that two incompatible drugs are precluded from being mixed in a single solution, or "treatment guideline" (col. 2, lines 16-19). Hence,

such a "process" of determination defines a "processor." Moreover, incorporation of the term "actually" at line 7 of claim 11 imparts no structural limitation to the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHD

Christine D Hopkins
Examiner
Art Unit 3735

Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735